CASE 33379 US-PCT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Rault et al.

APPLICATION NO: 10/572,687

FILED: August 8, 2006

FOR: Coated Tablets

Art Unit: 1618

Examiner: Nissa M. Westerberg

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

REPLY

Sir:

This is in response to an Office Action dated September 23, 2009.

No amendments have been made or new claims added.

REMARKS

Claims 17-23 are rejected under 35 USC 112 for failure to comply with the written description requirement. The rejection is traversed. The Examiner argues that since the exclusion of other actives is not specifically recited in the specification, recitation of only one active in the claims was not described in the specification so as to reasonably convey that the inventors had possession of the invention at the time of filing and therefore introduces new matter (stated to be a new "concept" by the Examiner). The Examiner requests support for the amended claims. The Examiner is directed to the entire specification in support. The specification is directed solely to a single-active tablet. Nowhere is there a teaching or suggestion that a second active be incorporated into said tablet. The exclusion of a second active in the claims is not new matter but merely a positive recitation of that which is inherent in the text. Inherency is not new matter.

Regarding applicants' comments below, previously presented arguments are incorporated herein, especially those of the Amendment dated July 24, 2009.

Claims 17-23 are rejected under 35 USC 103 as obvious over Bartholomaeus, USP 6,558,701 ("US'701") in view of DeNaan, US 2006/0051420 ("US'420") and SEPTIFILM. The rejection is traversed. There are various issues wherein applicants and the Examiner are in disagreement.

The first of these is the scope of the claims. Applicants have limited the scope by use of the limiting expression "consisting essentially of". The Examiner rejects this terminology and reads the claims broadly as "comprising". If the Examiner insists on re-drafting the claims to include that which applicants are not claiming, then reasonable argumentation is impossible. The Examiner's refusal to interpret the claims narrowly absent an indication in the claims or specification of what the basic and novel characteristics are is not understood. The Examiner's attention is directed to the entire specification, from which it is clear what the basic and novel characteristics of the claimed compositions are: applicants have described and are claiming a tablet with a single active ingredient which is surrounded by a single film coating. For the Examiner to insist that the claims read on more than this or that this is not clear from the specification is without merit. Consistent with her position, the Examiner argues that removal of a second active (tramadol) from US'701 is not required by the present claims or that the addition of the second active in a separate core does not materially affect the administration of the tablet. Only the improper re-drafting of the claims by the Examiner can support such statements. (Further, there are numerous side effects associated with the use of tramadol. These include constipation, dizziness, and

nausea. To say that there is no material effect from the inclusion of this second active is without medical basis.) It is deemed that the refusal of the Examiner to examine the claims as they are presented and not as she has redrafted them is error. Re-examination of the claims as presented is requested.

The Examiner's creative definition of a "separating" layer is also traversed. The meanings of separating layers and coating were discussed at length in the prior Amendment of July 24, 2009. These arguments have been dismissed but are again urged. The Examiner points out that a coating can be a separating layer because the coating can separate the tablet from the external environment. By this logic, an uncoated tablet packaged in a sealed bottle would be prior art because the sealed bottle separates the tablet from the environment. Thus, a sealed bottle qualifies as a separating layer by the Examiner's definition. However, words must be interpreted using their ordinary definitions unless an alternative meaning is clearly intended. Here there is no basis for creative definitions. Reading the art and the instant claims using the ordinary definitions of the terms therein, the difference between the art and the claims is clear.

The MPEP recites criteria which the Examiner should adhere to in making a case for *prima facie* obviousness. These include, but not limited to: 1) identifying the motivation found in the art to make the invention; 2) evaluating the art from the standpoint of one of ordinary skill in the art; 3) determining whether one of ordinary skill would be motivated to make the invention (i.e., to actually select the claimed subject matter from the art's genus; 4) considering the preferred species taught in the art; 5) considering the number of variables which must be selected from the art to make the invention; and 6) specifically articulating what teaching or suggestions in the art would have motivated one of ordinary skill to select the claimed species or subgenera. Finally, MPEP 2144.08 states that conclusory statements without articulated rationale or evidentiary support do not constitute sufficient factual findings. Without these, it is deemed that there is no basis for the Examiner's rejection based on obviousness. It is requested that the Examiner comply with these criteria and specifically point out how they have been met. It is deemed that the Examiner has not met the burden of proof necessary for a rejection under 35 USC 103. Stating that hardness and compressibility (neither of which, the Examiners agrees, is recited in the art or specification) are known to one of ordinary skill in the art does not support the rejection. The search for improving these qualities is merely an open invitation to experiment without guidance.

Regarding applicants' argument that DeHaan teaches away from the presently claimed type of coating, the Examiner replies that the mere disclosure in the art of more

than one alternative is not a teaching away. That may be so but is not relevant to the situation here. The Examiner's attention is directed to the arguments made in the Amendment of July 24, 2009. There it was pointed out that US'420 teaches a dosage form wherein the degradation of an active compound is delayed by use of a "wrap" coating, which may be a film, but is preferably a sugar or sugar film coating (abstract). Within the non-preferred genus "film" are listed a large number of film materials. It is taught that not all of the film materials have the desired stabilizing effect (**[0013]**). Thus, the Examiner's argument is that it would be obvious to one of ordinary skill in the art to select, without undue experimentation, a film to be chosen from a genus of less desirable films, after being made aware that some of these less desirable films are ineffective for stabilizing the active ingredient in US'420. It is deemed by applicants that one of ordinary skill in the art, having been advised that **films are less desirable** and that certain **films are ineffective** with regard to the active ingredient in US'420, would prefer to not use any of the less desirable films. It is rather more likely that said person would select a sugar or sugar film coating, all of which function well with the active compound of the reference and, thus, would appear to be more likely to succeed if applied to another active; i.e., **the reference teaches away from the coating of the present invention**. There no "reasonable expectation of success" from the use of these less desirable films. SEPTIFILM adds nothing to the Examiner's argument, since it only teaches that certain films were known in the art; i.e., that which is known from the specification (see Example 1).

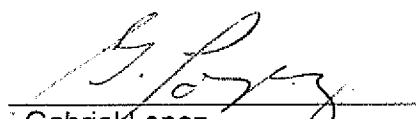
Claims 17-19 and 21-23 are rejected under 35 USC 103 as obvious over US'701, US'420, and SEPTIFILM in view of Gimet, USP 5,601,843 ("US'843"). The rejection is traversed. Comments regarding the three primary references are provided above and incorporated herein. The relevance of US'843 to the present invention is remote and adds nothing to the Examiner's arguments. US'843 teaches a tablet which comprises a core which contains an NSAID, said core encapsulated by a coating which contains a prostaglandin whose purpose is to counteract the possible side effects of the NSAID. The core and coating may be separated by an intermediate coating. *Contra* to the instant claims, which contain a single active in the core and no active in the coating, US'843 teaches a core covered by possibly four coatings, the outermost one of which (the mantle) contains a second active, whose purpose is to counteract the effects of the core. The coatings are described as enteric, aqueous enteric, overcoat, and mantle. Each of these has a different purpose and composition from the others. No one of them suggests the single film coating of the instant invention. The combination of these four references cannot be said to make obvious the instant claims.

Claims 17-19 and 21-23 are rejected under 35 USC 103 as obvious over US'701, US'420, and SEPTIFILM in view of Humbert-Droz, USP 6,083,531 ("US'531"). The rejection is traversed. Comments regarding the three primary references are provided above and incorporated herein. The relevance of US'531 to the present invention is remote and adds nothing to the Examiner's arguments. US'531 teaches a tablet which consists of an uncoated mixture of all the ingredients (col. 3, ll 39-44). The lack of coating is understandable, since the purpose of the composition is to be fast dissolving when placed in the mouth. The combination of these four references cannot be said to make obvious the instant claims.

Claim 24 is rejected under 35 USC 103 as obvious over US'843 in view of US'531, Voss, USP 4,690,927 (US'927), and US'420, and SEPTIFILM. The rejection is traversed. Comments regarding four of these references are provided above and incorporated herein. Regarding Voss, this reference teaches a coated tablet containing two actives, one of which is codeine. As pointed out above with regard to tramadol, codeine is an active with many known undesirable side effects. To say that there is no material effect from the inclusion of this second active (which the Examiner must in order to support this rejection) is without medical basis. Besides the arguments already made that these references either singly or in combination do not suggest the tablet of the instant invention, it is also strongly suggested by the Examiner's need to reply on five references to attempt to craft an obviousness rejection, that she has merely picked bits and pieces, in hindsight, from a large assemblage of references. Such hindsight collecting cannot be the basis for a rejection under 35 USC 103.

It is requested that the Examiner reconsider the rejections in view of these remarks and that the case be passed to issue.

Respectfully submitted,



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